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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,258	12/08/2000	Friedel Frauendorfer	H01.2-9587	7047

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	16

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/719,258	Applicant(s) FRAUENDORFER, FRIEDEL	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment D and Supplementary Information Disclosure received August 12, 2003 is acknowledged. Claims 1-14 are pending in this application.

Information Disclosure Statement

The information disclosure statement filed August 12, 2003 fails to comply with 37 CFR 1.98(a)(2), a copy of an English abstract of foreign patent has not been provided as asserted by applicant. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6-9, 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cade et al (WO 97/04755) in view of XP-002143507 or vice-versa.

XP teaches a gelatin capsule containing perilla oil, polyglycerol fatty acid ester, and monoglycerol fatty acid ester. One capsule contains 150mg of alpha-linolenic acid. The reference discloses that fats and oils that contain omega-3-polyenoic fatty acid and perilla, treat inflammatory bowel disease. Fats and oils containing preferably contain alpha-linolenic acid, eicosapentaenoic acid, or docosahexaenoic acid. See abstract.

XP does not specify the composition of the gelatin composition.

Cade et al teach hard gelatin with reduced water transport or water vapor permeation by either laminating a polymer layer onto the gelatin shell or adding an additive to the gelatin formulation. Additives such as xylitol, which are added to the gelatin solution, reduce water permeability and hygroscopicity (pg. 7). Cade discloses that capsules with low permeability to water vapor reduce sensitivity to storage conditions and improves the protection of the compositions contained within (pg. 1, first paragraph) since permeation by the environment may cause the composition within to agglomerate or degrade chemically (pg. 2, fourth paragraph). Furthermore, the rupture or dissolving time of the capsule decreases with the increasing amount of additive (page 6). Rupture times are taught in Table 9. Lastly the capsule can be used as a container for nutrients, medicaments, etc. (page 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Cade et al XP-002143507. One would be motivated to harden a gelatin capsule with xylose since Cade et al teaches this reduces permeability by the environment that chemically degrades the contents of the capsules. Alternatively, one would be motivated to include fatty acids into the gelatin capsule of

Cade et al to treat inflammatory bowel disease. It is the examiner's position that chemical degradation of the fill would read on the peroxidation of fatty acids since one mechanism for the deterioration of polyunsaturated fatty acids is oxidation in the presence of oxygen. Furthermore since Cade et al teach the use of sugar additives to prevent permeation of the environment into the capsule, it is implicit if the capsule prevents the presence of oxygen, the fatty acids will not undergo oxidation. In regards to the limitation "to an extent sufficient to inhibit peroxidation", it is the examiner's position that Cade's amount of xylose reads upon this broad limitation since the applicant has not provide any specific amount of xylose to demonstrate that Cade does not meet this limitation and since it is the inventive step of Cade to prevent the degradation of the contents inside the capsule.

Response to Arguments

Applicant argues that neither Cade nor XP teaches or suggests a gelatin capsule that is xylose-hardened to inhibit the peroxidation of polyunsaturated fatty acids. Further, applicant asserts that there is no motivation to combine the references. Applicant argues that Cade is only concerned with water transport and hygroscopicity and XP does not disclose the composition of the gelatin capsule.

Applicant's arguments have been fully considered but they are not persuasive.

In regards to the argument that the prior art is concerned with different problems then the inventive problem, the examiner points out that the use of patents as references are not limited to what the patentees describe as their own inventions or the

problems with which there are concerned. They are part of literature of the art, relevant for all they contain." See In re Heck.

As set forth in the rejection stated above, Cade teaches a xylitol-gelatin capsule. On [page 1, Cade disclose that the capsules improves storage conditions by improving the protection of fills from atmospheric water vapor. Additionally on page 6, Cadet discloses that the addition of a polyols such as sugars, sugar alcohols (xylitol), and polyvinyl alcohols significantly reduce water vapor permeability and capsule dissolving time. Oxidation is the process of oxidizing (the addition of oxygen); therefore by preventing vapor (a liquid suspended in air) from entering the capsule, oxygen is implicitly prevented from entering the capsule. Cade teaches the wide use of gelatin capsules in the pharmaceutical industry (see page 1) and teaches the incorporation of medicaments and nutrients in the inventive capsules. XP teaches the use of fatty acids to treat inflammatory bowel disease (IBD). Therefore, one would be motivated to utilize XP's fatty acids in Cade's capsules to treat IBD. The examiner does not have to have the same reason to combine as the applicant. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Further, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Cade teaches the advantages of using the xylitol capsules and suggests the use of medicaments or nutrients. Thus, Cade provides a suggestion for the use of desired medicaments. IT is deemed an obvious skill in the art that the incorporation of an active depends on the disease to be treated. One would expect similar results since XP teaches that gelatin capsules may be used to deliver the fatty acids. The motivation to use Cade's capsules for XP's active agent is that Cade clearly teaches the advantages of his capsules.

Lastly in regards to the new claims, the examiner points out that these claims are product by process claims. However, according to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Rejection of claims 1-7 and 9-14 under 35 U.S.C. 103(a) as being unpatentable over Yajima (4,525,306) in view of Cade et al (WO 97/04755) is maintained.

Yajima teaches the prevention of oxidation of oils and fats and soft capsules containing the oils. The reference disclose that the prevention of the oxidation of oils and fats is accomplished by physical means such as keeping oils and fats away from

oxygen and storing them at low temperatures, and adding antioxidants. See column 1, lines 5-20. Yajima teaches that although it is desirable from a nutritional point to ingest these fats and oils, fats and oils increase in their vulnerability to oxidation as the constituent fatty acids increase in the degree of in saturation. It is taught that fish oil contains high contents of eicosapentaenoic acid and unsaturated fatty acids and is effective for the prevention of thrombi. See column 2, lines 14-35.

Yajima does not specify the gelatin capsule composition.

Cade et al teach hard gelatin with reduced water transport or water vapor permeation by either laminating a polymer layer onto the gelatin shell or adding an additive to the gelatin formulation. Additives such as xylose, which are added to the gelatin solution, reduce water permeability and hygroscopicity (pg. 7). Cade discloses that capsules with low permeability to water vapor reduce sensitivity to storage conditions and improves the protection of the compositions contained within (pg. 1, first paragraph) since permeation by the environment may cause the composition within to agglomerate or degrade chemically (pg. 2, fourth paragraph). Furthermore, the rupture or dissolving time of the capsule decreases with the increasing amount of additive (page 6). Rupture times are taught in Table 9. Lastly the capsule can be used as a container for nutrients, medicaments, etc. (page 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Cade et al Yajima and incorporate xylose into the gelatin capsule. One would be motivated to do so since Cade et al teaches this reduces permeability by the environment that chemically degrades the contents of the

capsules and Yajima teaches the increased susceptibility of unsaturated fatty acids to deterioration via oxidation in the presence of oxygen. Alternatively, one would be motivated to include fatty acids into the gelatin capsule of Cade et al to prevent thrombi and for their nutritional value. It is the examiner's position that chemical degradation of the fill would read on the peroxidation of fatty acids since one mechanism for the deterioration of polyunsaturated fatty acids is oxidation in the presence of oxygen. In regards to the limitation "to an extent sufficient to inhibit peroxidation", it is the examiner's position that Cade's amount of xylose reads upon this broad limitation since the applicant has not provide any specific amount of xylose to demonstrate that Cade does not meet this limitation and since it is the inventive step of Cade to prevent the degradation of the contents inside the capsule.

Response to Arguments

Applicant argues that Cade disclose hard gelatin capsules with reduced water permeability to reduce the risk of destabilization of contains due to humidity. Applicant argues that Yajima discloses soft capsules containing oils and fats. Yajima prevents peroxidation of the fats and oils by adding an antioxidation. It is argues that one would not be motivated to utilize Cade's capsule with Yajima to solve the problem of oxidation. It is argued that Yajima teaches away form the claimed invention since applicant discloses that antioxidants are unnecessary.

Applicant's arguments have been fully considered but they are not persuasive. Yajima clearly teaches that instant fatty acids for nutritional reasons and teaches the use of capsules to deliver the oils. As discussed above, preventing peroxidation of the

capsule content is implicit since Cade's capsule improves "the protection of fills against atmospheric water vapor." Clearly, atmospheric vapor contains oxygen and thus this is an implicit teaching of preventing oxidation of the fill. Therefore, one would be motivated to combine the references to yield an additive effect since both references are directed towards protecting the fill from the environment.

In regards that Yajima's use of antioxidants teach away form the inventive formulation, the examiner points out the applicant relies on certain features that are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not exclude antioxidants.

Lastly in regards to the new claims, the examiner points out that these claims are product by process claims. However, according to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG
10/20/03

MICHAEL G. HARTLEY
PRIMARY EXAMINER